PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 8/00, A61N 1/365	A1	(11) International Publication Number: WO 99/07285 (43) International Publication Date: 18 February 1999 (18.02.99)

(21) International Application Number: PCT/SE98/01425

(22) International Filing Date: 30 July 1998 (30.07.98)

(30) Priority Data:
9702876-5 6 August 1997 (06.08.97) SE

(71) Applicant *(for all designated States except US)*: PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: HEMMINGSSON, Tryggve [SE/SE]; Sveavägen 49A, S-191 34 Sollentuna (SE).

(74) Agent: HOLMBERG, Anders; Pacesetter AB, Patent Dept., S-175 84 Järfälla (SE).

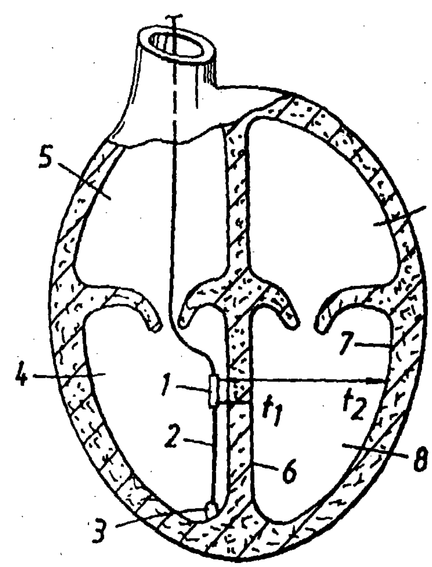
(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A CARDIAC MONITORING DEVICE AND A RATE RESPONSIVE PACEMAKER SYSTEM

(57) Abstract

A cardiac monitoring device comprises means (9) for transmitting a signal and receiving at least one echo of said signal reflected from at least one cardiac segment (6, 7, 16) a position of which, at least when reflecting said signal, is related to the cardiac performance of a heart, and, means provided to register a delay (t_1, t_2) between the transmission of the signal and the receipt of said echo, and to derive from the delay (t_1, t_2) the position of said cardiac segment (6, 7, 16). Furthermore, the device comprises means (11) provided to derive from said position the cardiac performance. The inventive device may also form part of a rate response pacemaker system.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

A cardiac monitoring device and a rate responsiv pacemaker system

BACKGROUND OF THE INVENTION AND PRIOR ART

The present invention relates to a cardiac monitoring device comprising means for transmitting a signal and receiving at least one echo of said signal reflected from at least one cardiac segment, a position of which, at least when reflecting said signal is related to the cardiac performance of a heart, and means provided to register a delay between the transmission of the signal and the receipt of said echo, and to derive from the delay the position of said cardiac segment.

The invention also relates to a rate responsive pacemaker system comprising such a device.

As the device is particularly suited for an application in which it is arranged to register the position of a cardial wall segment, it will, by way of example only, be described in relation to such an application hereinafter. Thereby, the cardiac performance refers to cardiac output and/or other parameters related to cardiac frequency, such as beat volume, cardiac contractility etc.

Such a device is disclosed in US patent number 3,938,502, telling about a device for examining a hollow organ, such as a heart, said device being of a type comprising a catheter which is to be placed inside the hollow organ and which is provided at its end with a circumferencially arranged, equidistantly distributed elements, each of which serves both for the transmission and reception of ultrasonic waves. In order to make it possible to completely visualize the moving cardiac structure, such as heart walls and heart valves, surrounding the catheter, at any moment, the device presents a large number of elements which show very little directivity in a plane perpendicular to the axis of the catheter, the elements being so dimensioned in axial direction that the major part of acoustic energy in transmission is confined to a plane perpendicular to the axis of

the catheter. Moreover, it presents an excitation device which successively excites groups of adjacently arranged elements at a rate of at least 25 times per second. There are time delays for so delaying the transmitted and the received pulses for the elements of a group that the differences in travel times among the elements for the pulses to or from a line laying in the plane perpendicular to the catheter axis and being perpendicular to the centre line of the group are compensated. There is further an adder for the summation of the echo pulses brought into coincidence by the time delays. A device is used for visually displaying the part of the examined hollow organ surrounding the catheter. This patent referred to thus shows an equipment for direct imaging by means of a so called brightness mode (B-mode) ultrasound. The catheter described is meant, in the first place for examining a visualizing a heart, but is obviously not meant for implantation and would not possibly be used for such a purpose as it is considered highly energy consuming and would be of unacceptable size and weight for operation as an implantable equipment.

EP 0 503 839 discloses a method and an apparatus for chronically monitoring the hemodynamic state of a patient using Doppler ultrasound. Such a method and apparatus is used for regulating blood flow within the cardiovascular system in a closed-loop control system using ultrasound measurement techniques to determine a hemodynamic status of a patient and to derive a control parameter for modulating the hemodynamics of the system using electrical or pharmaceutical therapy. Heart contractility and the blood flow output from the heart is monitored in order to control an implantable cardiac assist or therapy device to maintain cardiac output without invading the left heart or the arterial system of the patient. Thus, the pacing rate of a cardiac pacemaker may be based on the determination of the cardiac output estimated by this device. The device is arranged to measure the cardiac output using Doppler ultrasound techniques in which a measuring transducer is implanted within the right heart and directed towards the left ventricle or aortic route. The transducer radiates acoustic energy at ultrasonic frequencies, then the device determines blood flow velocity by

receiving and processing the resulting echo signals and measuring the shift in frequency of the returning echoes in comparison to the transmitted waves. The integral of the mean velocity curve is an accurate representation of stroke volume and cardiac output. However, the device is not provided to register the delay between the transmission of the signals and the receipt of the echoes thereof in order to derive from the delay a position of a certain cardiac segment. Moreover, a Doppler equipment to be used in the above application requires quite a lot of energy for its operation, and the output acoustic energy is likely to be too high to be used for permanent operation in a human body.

However, such a device as the one disclosed in EP 0 503 839 gives a possibility to register the hemodynamic situation in the systemic high pressure circulation of a heart, that is in the left atrium and left ventricle thereof, without needing to be located in said high pressure system. This is an advantage in comparison to prior pacemaker systems that are developed primarily to detect physiologic changes in the right atrium and/or right ventricle even though the action of the pulmonary or right side of the heart, only to a minor degree mirror the hemodynamic situation in the high pressure part of the heart system.

According to modern research and scientific publications as by Baan et al (Baan J. Jong TT. Kerkhof PL. Moene RJ. van Dijk AD. van der Velde ET. Koops J. Continuos stroke volume and cardiac output from intra-ventricular dimensions obtained with impedance catheter. Cardiovascular Research 1981 Jun;15(6):328-34), a very good correlation exists between left ventricular diameter and cardiac output performance. Thereby the changes in intra-ventricular dimensions have been measured by means of electrical impedance. For this purpose, a catheter has been equipped with a number of electrodes spaced over a distance equal to the long axis of the left ventricle into which the catheter has been introduced. A constant current was imposed between the outermost electrodes while the inner ones were used to measure resistance of volume segments of the blood contained within the ventricular cavity. The difference in

resistance at the beginning and the end of ejection was proportional to the contribution of each segment to stroke volume. The best correlation of left ventricular diameter to cardiac output performance was received when measuring in the middle of the axial length of the left ventricle.

SUMMARY OF THE INVENTION

One object of the present invention is to provide a cardiac monitoring device which permits to estimate the total cardiac performance of a heart, including the performance of the high pressure side of said heart, without interfering the function of the heart or being easily interfered by the function of the heart. Moreover, the device should be of a type that is implantable in mammals, and particularly human beings, and which permits to be used in such an application for a significant period of time. The device should also be of a type that requires a minimum of power consumption and is simple as to its construction.

This object is obtained by means of a device of the initially defined type, which is characterized in that it comprises means provided to derive from said position the cardiac performance. By directing the transmitted and correspondingly received signal or signals towards a cardiac segment the position of which correlates very well to the cardiac performance, that is the cardiac output performance, the device may be used to provide a pacemaker with information concerning said performance. Such information may then be used by the pacemaker system in order to suitably control the very pacing of the heart. The inventive device permits monitoring the condition of the left, high pressure side of the heart, while being positioned at another location, for instance in the pulmonary side of the heart.

According to a preferred embodiment of the device, the device is arranged to be positioned in at least one of the right atrium and right ventricle of a heart. Thereby, left atrial or ventricular movements and dimensions may be detected in a minimally invasive way while

avoiding those problems that may appear if the device would be located in the left part of the heart, that is the left atrium or ventricle.

According to another preferred embodiment of the device, it is arranged to direct said signal towards at least one of a left atrium and a left ventricular wall of a heart, said wall defining said cardiac segment. Thereby, one particularly takes advantage of the fact that echoes of the signal may be received from said walls and that the position of said walls at a certain movement during a cardiac cycle may correlate to the inner diameter of the left atrium or ventricle at that specific movement or, at least, to the volume of the left atrium or ventricle of the heart, said diameter or volume correlating to the cardiac output performance. Thus, by deriving the position of said wall, a precise estimation of the momentary cardiac performance may be obtained.

According to another preferred embodiment of the device, the latter is arranged to direct said signal towards the medial and lateral endocardial wall of the left ventricle respectively, said walls defining said cardiac segment, and to derive from the echo delay difference therebetween the distance between said walls, said distance corresponding to the cardiac performance. Such an arrangement is particularly advantageous as it has been shown that the distance between these walls correlates very well with the cardiac output, In order to achieve this, the device is preferably arranged at a catheter or the like arranged to be inserted in or near the heart and anchored therein in quite a fixed position.

According to another preferred embodiment, the inventive device forms a part of a rate responsive pacemaker system and is arranged to provide said system with cardiac performance information. Thereby, the very pacing may be performed with respect to the cardiac performance in every single situation. For example, in a DDDR-mode, the atrium and the ventricle operate in synchrony. At high atrial rates this synchronous behaviour may be inappropriate or harmful. The pacemaker, by means of the inventive device, detects when synchronous behaviour is harmful by measuring the cardiac

output. While an atrial rate causes an elevation in cardiac output, the pacemaker allows the ventricle to respond to the atrial rate. When further increases in atrial rate lead to a sustained degradation in cardiac output, the pacemaker no longer allows synchronous pacing. By measuring cardiac output, the pacemaker system may determine when ventricular activity should not follow natural atrial heart beats and is able to adjust to a suitable pacing mode. In addition, using an indication of cardiac output, the pacemaker system can determine whether the heart is successfully responding to a pacing stimulus of a particular amplitude and pulse duration.

According to another preferred embodiment of the device, said transmitting means are provided to transmit ultrasound according to the A-mode principle, defining said signal. Thereby, the power consumption is minimal due to the fact that the periodical measurement frequency may be low, for example twice per cardiac cycle or less, and that, ideally, transmission may be performed in one direction only.

According to another preferred embodiment of the device, the transmitting and receiving means comprise at least one ultrasound crystal, arranged onto a pacemaker electrode. By arranging said crystal onto the electrode a very precise position of the crystal may be defined. For example, a tip at the end of the electrode is arranged to be anchored at the very bottom of the right ventricle, resulting in the electrode extending through the ventricle in a very well defined way, thereby making it possible to locate said crystal with good precision at a suitable location along the electrode.

According to another preferred embodiment of the device the transmitting and receiving means comprise an array of ultrasound crystals, distributed around the periphery of a pacemaker electrode, each of the ultrasound crystals being arranged to individually transmit and receive ultrasound pulses in a co-ordinated manner. This arrangement is to assure optimal transmission and reception performance even at possible rotation of the pacemaker electrode at the time of implantation or later. By checking which crystal receives

the most appropriate echo, transformation and receipt of the ultrasound signals may then be performed with that single crystal. There is always at least one crystal active with optimal measurement performance and directed in a correct direction, e.g. towards the site of the left ventricle where the wall movements correspond best to the volume changes thereof and are large enough to be easily detected. For example, the crystals of the array may be arranged to scan their detection area at predetermined or optional occasions and the device may comprise means to choose, by way of scanning, the best measured echo performance in order to choose which crystal or crystals are to be used for transmission until the next scanning event. By only receiving echoes within a certain temporal window and studying the amplitudes of the echoes received by the respective crystal within said temporal windows, it is possible to determine which echo performance is the best and most suitable one for further measurement. Preferably, the device is connected to or comprises a logical unit of a pacemaker system, said logical unit being arranged to treat the information from each individual crystal and to determine which echo performance is the best.

According to another preferred embodiment the device comprises means for triggering the transmission of said single crystal at desired moments of a cardiac cycle from sensed IEGM-information by a pacemaker electrode connected thereto. Thereby, the device is arranged to trigger two consecutive transmissions at selected moments during one or two cardiac cycles, e.g. when the ventricular volume is supposed to be at or near its minimum and maximum respectively, in order to derive the positions of said cardiac segment at said moments in order to estimate said respective volume, corresponding to the cardiac performance. By performing the transmission and receipt at such moments a very good correlation between the position of the respective cardiac segment, for instance the left ventricular walls, and the cardiac output is obtained. Particularly, the difference between minimum and maximum inner diameter of the left ventricle has a good correlation to the cardiac

output, said correlation being taken advantage of by this specific arrangement of the device.

Another object of the present invention is to provide a rate responsive pacemaker system capable of estimating the cardiac performance, that is a cardiac output, and to use this information as a parameter in order to control its pacing or other operation.

Such a rate responsive pacemaker system is characterized in that it comprises a device according to the invention as previously described.

Further advantages and features of the present invention will appear in the following, detailed description and the other dependent claims.

BRIEF DESCIPTION OF THE DRAWINGS

An embodiment of the device according to the present invention will now, by way of example only, be described with reference to the attached drawings, on which:

Fig 1 is a schematic view, showing the inventive device positioned on a pacemaker electrode inside the right ventricle of a heart.

Fig 2 is a diagram showing amplitude versus time for pulse echoes from the ventricular walls according to Fig 1.

Fig 3 is a schematic block diagram of the rate responsive pacemaker system of the invention, and

Fig 4 is a detailed view, showing an array of ultrasound crystals arranged in a twisted manner or helically around the periphery of a pacemaker electrode.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

According to Fig 1 a simple amplitude mode (A-mode) ultrasound detector 1 is mounted at the distal end of a pacemaker electrode 2. A tip 3 of the electrode 2 is anchored at or near the apex of the right ventricle 4 of a heart 5. The detector 1 is arranged to detect the position of the medial 6 and lateral 7 endocardial wall of the left ventricle 8 respectively, said wall defining a cardiac segment from which an echo of a signal transmitted by the device is received by said device.

The device comprises means 9 for transmitting a signal and receiving at least one echo of said signal reflected from at least one cardiac segment, here constituted by said medial and lateral endocardial walls 6, 7. The transmitting and receiving means 9 comprise an array of ultrasound crystals, helically arranged around the periphery of the electrode 2. Here, ten crystals are provided. Each of the ultrasound crystals 9 is arranged to individually transmit and receive ultrasound information, alone or simultaneously with other crystals, in a co-ordinated manner and by transmission and reception of ultrasound pulses as shown in the diagram of Fig 2. The ultrasound transmission of the device 1 is triggered by means of a pacemaker system according to Fig 3 at the desired moment of cardiac cycles and from sensed IEGM-information by the pacemaker electrode. Thereby, each ultrasound crystal 9 is electronically connected to the very pacemaker system. The connection between the ultrasound leads and a corresponding adapter (not shown) of a pacemaker housing is made via small connectors or via a data interface whichever is easier to develop and manufacture.

The transmitting and receiving means 9 are arranged at such a distance from the tip 3 of the electrode 2 that they will be located approximately at the middle of the right ventricle in the lengthwise direction thereof when the tip is anchored, preferably at or near the apex of said ventricle.

The means 9 are arranged to transmit ultrasound with an adjustable frequency of approximately 4-15 megahertz for optimal echo

reception at a distance of approximately 3-15 cm. The ultrasound pulses transmitted are about 1 millisecond wide and of an amplitude that is to be selected according to minimal detection level and distance requirement. The reception of the ultrasound pulses or signals is made according to a programmable calculated temporal window in such a manner that the corresponding ultrasound echo is received from a distance corresponding to the endocardial walls 6, 7 of the left ventricle. Accordingly, by using such a temporal window, it is possible to avoid receiving a disturbing echo from the adjacent medial endocardial wall of the right ventricle 4 when the device is located as in Fig 1. The time delay t of reflected echo pulses from an impedance altering interface of e.g. heart tissue is equal to 2 x L/V, where L is the distance from the means 9 to the interfacing tissue detected and V is the ultrasound velocity in the heart tissue.

Furthermore, the inventive device is connected to and forms a part of a rate responsive pacemaker system, schematically represented in Fig 3 by means of a block diagram, said block diagram comprising a programming block 10, arranged to be programmed by means of a separate programmer (not shown) in a way known per se.

The system also comprises a control logic block 11, a pacemaker electronics and logic block 12, a pulse generator block 13 and a transmitter/receptor block 14. The transmitter/receptor block 14 is adapted to communicate with the transmitting and receiving means 9, here represented by an ultrasound crystal array block 15. The pulse generator 13 is arranged to communicate with the pacemaker electronics and logic 12 and to receive therefrom a clock frequency. The pulse generator 13 is also arranged to transmit pulses to the transmitter/receptor block 14. Furthermore, the pacemaker electronics and logic block 12 is arranged to transmit a clock frequency to the transmitter/receptor block 14. The control logic block 11, which receives control information from the programming block 10, is arranged to control the pacemaker electronics and logic 12 as well as the transmitter/receptor block 14 and to receive information therefrom concerning transmission of signals, reception

of echoes thereof, delays and delay differences as defined above. Thereby, the pacemaker system is able to take advantage of this information and use it as parameters in order to better control the operation and particularly the pacing of said system.

According to the invention the device is arranged to trigger at least two consecutive transmissions with corresponding receipts in one of the systolic phase of the cardiac cycle, the diastolic phase of the cardiac cycle, both the systolic and the diastolic phase of the same cardiac cycle, a desired phase of the cardiac cycle with an optional time difference between two consecutive transmissions, and a desired phase of the cardiac cycle selected via separate sensing ability of the rate responsive pacemaker. Preferably, the device receives control information regarding how to perform these measurements through a pacemaker system similar or identical to the one schematically represented in Fig 3.

As to the transmitting and receiving means 9, a physician may manually by telemetrical programming features or by using an automatic sensing algorithm built into the system control the operation mode of the inventive device. For example, he may program the programming block of the system such that the ultrasound crystals of the array scan the detection area at predetermined occasions, for example once a week, in order to choose the best measured echo performance and which crystal or crystals to be used for transmission of the signals and reception of echoes thereof. Preferably, the control logic block 11 is also arranged or programmed to treat the transmission and receipt information and to derive therefrom the position of the medial and lateral endocardial wall of the left ventricle of a heart and to derive therefrom the corresponding volume of the left ventricle at each measuring occasion. By measuring the end-diastolic volume EDV and the end-systolic volume ESV and subtracting these dimension data EDV-ESV a relative measure of the stroke volume SV of the left ventricle may be obtained. As the stroke volume is a parameter related to the cardiac output CO of the heart (CO = Heart rate x SV) the pacemaker system is preferably arranged to use these data in

order to control its pacing rate. Particularly, the system may be arranged to inhibit further increase of the pacing rate as, during an increase of the pacing rate, the stroke volume reaches a certain level where further increase of the pacing rate only would result in an even smaller stroke volume and thus would not be a correct measure to increase the total cardiac output.

This method permitted by the inventive device gives an indirect measure of cardiac output (through diameter variations during a cardiac cycle), but as the most important information from a sensor for rate responsive pacing is used to correct earlier sampled information and preset the desired heart rate, the A-mode ultrasound detector gives appropriate information to fulfil this task. As this sensor information is collected directly from the left ventricle of the heart and not limited to the right ventricle as with the main part of the cardiac pacing sensor techniques, it gives the optimal information from the cardiovascular situation for hemodynamic rate adapted pacing.

Of course a plurality of variations and modifications of the present invention should be obvious for a man skilled in the art without thereby departing from the scope of the invention.

For example the measurement logics could be refined in future applications to measure absolute cardiac volumes. Furthermore, the transmitting and receiving means 9 do not need to be positioned onto a pacemaker electrode provided with a ring or a tip 3, but could as well be attached onto a separate lead or electrode adapted to be positioned inside or outside the very heart and not necessarily anchored in a cardiac wall. However, it has been found favourable to attach the transmitting and receiving means 9 onto a pacemaker electrode, the tip of which is arranged to be anchored at the apex of the right ventricle. Thereby, the distance from the very tip 3 to the transmitting and receiving means 9 preferably should be such that the latter then would be located approximately opposite to the point of the left ventricle 8 where the contraction thereof is as clear and easy to detect as possible and corresponds to the volume change of

the ventricle. Thereby, the distance from the tip 3 to the transmitting and receiving means 9 should be in the order of 2-6 cm for use in the heart of a full grown adult.

Moreover the amount of crystals in the array may be more or less than ten as shown. In order to obtain a better precision a substantially larger number might be used, e.g. thirty crystals uniformly distributed around the periphery of the electrode.

Preferably, the crystals, or the array thereof, may also be displaceably arranged along the longitudinal axis of the electrode or lead, thereby admitting adjustment to different heart sizes or to the growing heart of a child equipped with the device, or the positioning of the device in the atrium or ventricle.

Preferably, the operation of the inventive device may be used in a closed loop-system.

Claims

1. A cardiac monitoring device, comprising
- means (9) for transmitting a signal and receiving at least one echo of said signal reflected from at least one cardiac segment (6, 7, 16), a position of which, at least when reflecting said signal, is related to the cardiac performance of a heart, and
- means (11) provided to register a delay (t_1, t_2) between the transmission of the signal and the receipt of said echo, and to derive from the delay (t_1, t_2) the position of said cardiac segment (6, 7, 16), characterized in that it comprises
- means (11) provided to derive from the position the cardiac performance.

2. A device according to claim 1, characterized in that it is arranged to be positioned in at least one of the right atrium (5) and right ventricle (4) of a heart.

3. A device according to claims 1 or 2, characterized in that it is arranged to direct said signal towards at least one of a left atrial (16) and a left ventricular wall (6, 7) of a heart, said wall defining said cardiac segment.

4. A device according to claim 1, characterized in that it is arranged to direct said signal towards the medial (6) and lateral endocardial (7) wall of the left ventricle respectively, said walls defining said cardiac segment, and to derive from the echo delay difference (t_2 - t_1) therebetween the distance between said walls, said distance corresponding to the cardiac performance.

5. A device according to any one of claims 1 to 4, characterized in that it forms a part of a rate responsive pacemaker system and is arranged to provide said system with cardiac performance information.

6. A device according to any one of claims 1 to 5, characterized in that said transmitting means (9) are provided to transmit ultrasound according to the A-mode principle, defining said signal.

7. A device according to any one of claims 1 to 6, characterized in that said transmitting and receiving means (9) comprise at least one ultrasound crystal, arranged onto a pacemaker electrode (2).

8. A device according to any one of claims 1 to 7, characterized in that said transmitting and receiving means (9) comprise an array (15) of ultrasound crystals, distributed around the periphery of a pacemaker electrode (2).

9. A device according to claim 8, characterized in that each of the ultrasound crystals (9) is arranged to individually transmit and receive ultrasound pulses in a co-ordinated manner.

10. A device according to any one of claims 1 to 9, characterized in that it comprises means (11, 12, 13, 14) for triggering the transmission of said signal at desired moments of a cardiac cycle from sensed IEGM-information by a pacemaker electrode (2) connected thereto.

11. A device according to any one of claims 1 to 10, characterized in that it is arranged to trigger two consecutive transmissions at moments during one or two cardiac cycles when the ventricular volume is supposed to be at or near its minimum and maximum respectively, in order to derive the positions of said cardiac segment at said moments in order to estimate said respective volume, corresponding to the cardiac performance.

12. A device according to any one of claims 1 to 11, characterized in that it is arranged to trigger at least two consecutive transmissions with corresponding receipts in one of

- the systolic phase of the cardiac cycle,
- the diastolic phase of the cardiac cycle,
- both the systolic and diastolic phase of the same cardiac cycle,

- a desired phase of the cardiac cycle with an optional time difference between two consecutive transmissions, and
- a desired phase of the cardiac cycle selected via separate sensing ability of a rate responsive pacemaker.

13. A rate responsive pacemaker system, characterized in that it comprises a device according to any one of the preceding claims.

Fig. 1

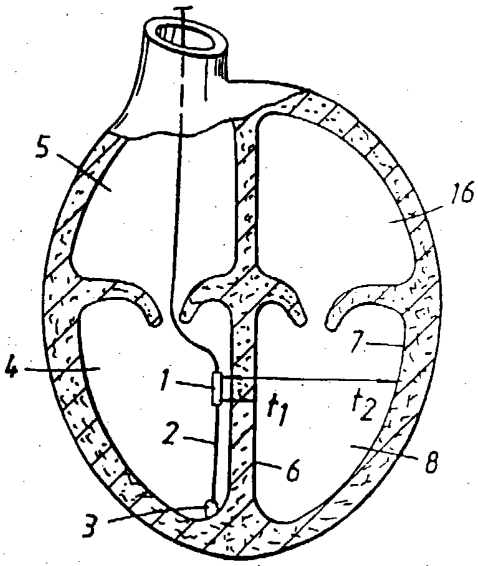


Fig. 3

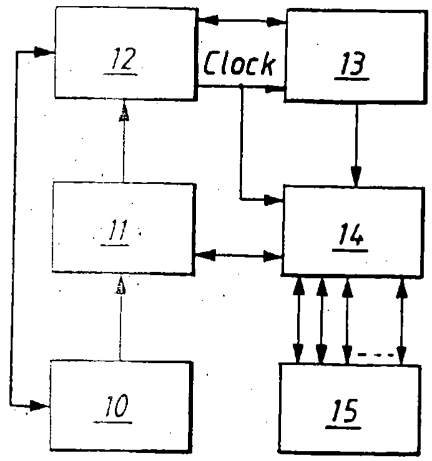


Fig. 2

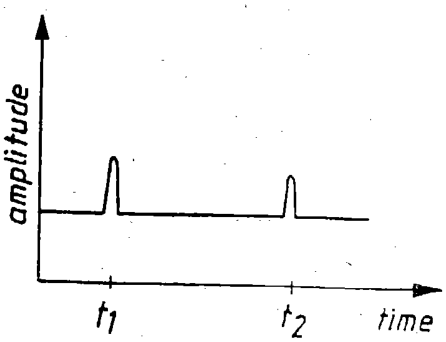
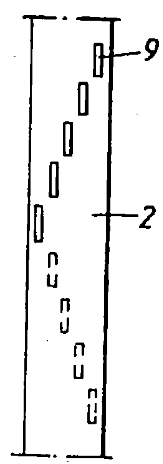


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 98/01425

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 8/00, A61N 1/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4109644 A (G.K.KOJIMA), 29 August 1978 (29.08.78), column 3, line 21 - line 10, abstract --	1-13
Y	EP 0503839 A2 (TELETRONICS N.V.), 16 Sept 1992 (16.09.92), column 15, line 14 - line 22, figure 8a, abstract --	1-13
A	US 5465721 A (S.KISHIMOTO ET AL), 14 November 1995 (14.11.95), see the whole document -- --------	1-12

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 December 1998	17 -12- 1998
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Patrik Blidefalk Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/12/98

International application No.
PCT/SE 98/01425

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4109644 A	29/08/78	NONE	
EP 0503839 A2	16/09/92	DE 69226547 D	00/00/00
		JP 6246010 A	06/09/94
		US 5188106 A	23/02/93
US 5465721 A	14/11/95	JP 7289545 A	07/11/95
		JP 8000627 A	09/01/96
		JP 8000625 A	09/01/96